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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,538	KIRIBAYASHI ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 01/06/10.

The amendment filed 01/06/10 affects the application, 10/533,538 as follows:

1. New claims 33-36 have been added. The rejections made under 35 U.S.C. 103(a) are maintained.
2. The responsive to applicants' amendments and arguments is contained herein below

Claims 11-32 are pending in the application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites the phrase "peritoneal dialysis solution that does not contain adenosine triphosphate and adenosine triphosphate." However, the claim is indefinite since it is unclear how a solution can contains and simulataneously not contain the same substance or ingredient (adenosine triphosphate).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al. (US 5,871,477).

Claim 11 is drawn to a peritoneal dialysis method for treating a peritoneal iniury or for treating a cell injury caused by sugar comprising: administering to a patient having a peritoneal injury or a cell injury caused by sugar a dialysate comprising adenosine triphosphate or a salt thereof. Claim 12 is drawn to the peritoneal dialysis method of claim 11, wherein said patient is suffering from a renal disease, and said dialysate is administered intraperitoneally via a catheter implanted in the peritoneal cavity. Claims 13-17 are drawn to said method wherein the adenosine triphosphate or a salt thereof is of specific concentration range, wherein the composition further comprises glucose, and an electrolyte, glucose of specific concentration range and further administering high level glucose.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it

should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan.

Claim 18 is drawn to a treating method for peritoneal injury, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof. Claim 19 is drawn to a treating method for cell injury caused by sugar, characterized by

administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof. Claim 20 is drawn to the method as described in claim 19, wherein the cell injury caused by sugar is peritoneal mesothelial cell injury caused by glucose. Claims 31-32 are drawn to said method comprising administering a solution containing ATP or salt thereof, glucose of specific concentration range, and electrolytes.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al.

disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate ((see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject.

In claim 21, applicant claims a peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar, comprising: administering into the peritoneal cavity of a subject having a peritoneal injury or a cell injury caused by sugar an effective amount of a composition comprising adenosine triphosphate or a salt thereof. Claims 22-30 are drawn to said method wherein said composition used contains specific electrolytes, organic acid, lactic acid and which has specific osmotic pressure, and wherein the subject has specific conditions.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate ((see col. 2, lines 5 to 46, especially lines 34-46)

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan. It should be noted that it is obvious to a skill artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject.

Claim 33 is drawn to a peritoneal dialysis method comprising: administering to a patient in need of dialysis a dialysate comprising adenosine triphosphate or a salt thereof. Claims 34 is drawn to the method of claim 33 comprising administering specific dialysate that does not contain ATP and ATP. Claim 35 and 36 are drawn to the said method wherein the adenosine triphosphate is of specific concentration range and wherein the said patient has specific condition,

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and

col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to use a peritoneal dialysis method comprising to treat peritoneal injury such as peritonitis in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to use a peritoneal dialysis method comprising to treat peritoneal injury such as peritonitis in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or

composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan. It should be noted that it is obvious to a skill artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. Also, it should be noted that it is obvious to use additional dialysate that contains other ingredients like those suggested by Isono et al. based on need such as the severity of the condition and the type, age and weight of the patient treated.

Response to Arguments

Applicant's arguments with respect to claims 11-36 have been considered but are not found convincing.

The applicant argues that while Isono describes conventional dialysis solutions that do not contain ATP (see col. 2, lines 5-33) and depicts conventional methods of dialysis in Fig. 13, it does not disclose or suggest adding ATP to a dialysis solution. However as set forth in the above rejection, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests

that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis.

Furthermore, with respect to Fig. 13, the figure indicates or suggest that the peritoneal dialysate composition can be administered to a patient abdomen, or peritoneum or peritoneal cavity via the depicted medical container. Moreover, Isono et al. disclose that the medical container according to the present invention is provided with the isolated or connected compartment. The bicarbonate is stored in the compartment. This bicarbonate is mixed with the electrolyte solution (i.e., the base solution) when the openable means is opened at the time of use. As a consequence, the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) which is used for administration, dialysis or the like contains bicarbonate ions at the time of use. Described specifically, the amount of an electrolyte such as an acetate or a lactate can be reduced in accordance with the proportion of the bicarbonate so that bicarbonate ions are **directly introduced into the body to maintain** the in vivo concentration of bicarbonate ions constant (see col. 4, lines 17-34). Thus, the fact that Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-34), means or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

The applicant argues that there is no suggestion in Isono to add adenosine triphosphate to a dialysate such as that described in col. 2, lines 10-17. Rather, col. 2, lines 35-47 of Isono specifically refer to modify organ preserving solutions like the glucose-free Eurocollin's

solution described in col. 2, lines 26-34 with a variety of proposed additives. However, as set forth in the rejection above, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition disclosed by Isono et al. can be administered into the peritoneal cavity (see rejection above).

The Applicant argues that the while the Official Action ("OA") explicitly states that "Isono et al.'s composition does not contain adenosine triphosphate" (OA, bottom of page 3), it contends that such a dialysis solution is suggested by Isono. However, Isono clearly distinguishes amongst the different physiological solutions that may be contained within the medical container it discloses. Namely, cols. 1 and 2 of Isono distinguish between (i) infusion solutions, (ii) dialysate, and (iii) an organ (tissue) preserving solution, see col. 1, lines 21-24, and col. 1, lines 51-col. 2, line 4 describing infusion solutions, col. 2, lines 5-21 which disclose dialysates, and col. 2, lines 35-47 which describe organ-preserving solutions. It is evident from these portions of the reference that Isono recognized the significant compositional differences between a peritoneal dialysis solution and one used to preserve organs.

However as set forth in the above rejection, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore,

Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. Moreover, Isono et al. disclose that the medical container according to the present invention is provided with the isolated or connected compartment. The bicarbonate is stored in the compartment. This bicarbonate is mixed with the electrolyte solution (i.e., the base solution) when the openable means is opened at the time of use. As a consequence, the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) which is used for administration, dialysis or the like contains bicarbonate ions at the time of use. Described specifically, the amount of an electrolyte such as an acetate or a lactate can be reduced in accordance with the proportion of the bicarbonate so that bicarbonate ions are **directly introduced into the body to maintain** the in vivo concentration of bicarbonate ions constant (see col. 4, lines 17-34). Thus, the fact that Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-34), means or suggests that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

The applicant argues that with regard to point (2) above, since col. 2 of Isono does not suggest a peritoneal dialysis solution containing adenosine triphosphate, it also cannot suggest the claimed method of performing peritoneal dialysis with a solution containing ATP. Isono suggests that ATP might be one ingredient useful in an "organ preservation" solution, but does not suggest and fails to recognize the value of ATP in a peritoneal dialysis solution. Assuming arguendo, that Isono did suggest a peritoneal dialysis solution containing adenosine triphosphate (ATP), which it does not, it provided no suggestion select such a dialysate for the treatment of peritoneal injury or cell injury caused by sugar.

However, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. Consequently, one having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

The Applicant argues that the Examiner has not pointed out any other portion of Isono suggesting administering "a dialysate comprising adenosine triphosphate" to a patient having a peritoneal injury or cell injury caused by sugar" as required by independent claim 11. However, Isono et al. suggest treating the same condition as that is treated by applicant regardless of the cause of said condition. As example, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The Applicant argues that adenosine triphosphate is not recognized as a conventional component of dialysis solution as evident from the citations below: (1) Wikipedia (last modified on 2 January 2010 at 18:56; Peritoneal dialysis (PD) is a treatment for patients with severe chronic kidney failure. The process uses the patient's peritoneum in the abdomen as a membrane across which fluids and dissolved substances (electrolytes, urea, glucose, albumin

and other small molecules) are exchanged from the blood. However, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. Also, Isono et al. disclose that the medical container according to the present invention is provided with the isolated or connected compartment. The bicarbonate is stored in the compartment. This bicarbonate is mixed with the electrolyte solution (i.e., the base solution) when the openable means is opened at the time of use. As a consequence, the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) which is used for administration, dialysis or the like contains bicarbonate ions at the time of use. Described specifically, the amount of an electrolyte such as an acetate or a lactate can be reduced in accordance with the proportion of the bicarbonate so that bicarbonate ions are **directly introduced into the body to maintain** the in vivo concentration of bicarbonate ions constant (see col. 4, lines 17-34). Thus, the fact that Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-

34), means or suggests that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

The applicant argues that with regard to point (3) above, Isono cannot provide a reasonable expectation of success for the invention which as shown by the experimental data of record reduces peritoneal injury caused by glucose by incorporating ATP.

The applicant argues that while Isono describes conventional dialysis solutions that do not contain ATP (see col. 2, lines 5-33) and depicts conventional methods of dialysis in Fig. 13, it does not disclose or suggest adding ATP to a dialysis solution. However as set forth in the above rejection, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. Consequently, one having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition

comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
March 27, 2010.

/Shaojia Anna Jiang/
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